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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/671,524	09/27/2000	Brian G. Scrivens	P-5016	6700

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EXAMINER

STOCK JR, GORDON J

ART UNIT	PAPER NUMBER
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2877

DATE MAILED: 02/13/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/671,524

Applicant(s)

SCRIVENS ET AL.

Examiner

Gordon J Stock

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on _____.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-23 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-23 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 27 September 2000 is/are: a) ☐ accepted or b) ☒ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____.

DETAILED ACTION

Drawings

1. The drawings are objected to because 4 and 5 of Fig. 2 need to point to a designation. A proposed drawing correction or corrected drawings are required in reply to the Office action to avoid abandonment of the application. The objection to the drawings will not be held in abeyance.

Claim Rejections - 35 USC § 112

2. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

3. **Claim 6-9, 19, 20, 22, and 23** are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

4. The term "about" in **claims 6-9, 19, 20, 22, and 23** is a relative term that renders the claim indefinite. The term "about" is not defined by the claim, the specification does not provide a standard for ascertaining the requisite degree, and one of ordinary skill in the art would not be reasonably apprised of the scope of the invention. "About" renders the dimensions of the separation channels and the compartments indefinite.

Claim Rejections - 35 USC § 103

5. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

6. **Claims 1, 2, 6, 7, 18, 19, and 20** are rejected under 35 U.S.C. 103(a) as being unpatentable over **Hillman et al. (5,164,598)** in view of **Prevost et al. (5,466,384)**.

As to **claim 1**, Hillman discloses a capillary flow device and method comprising:

a) providing an apparatus comprising:

a sample chamber comprising: two containment walls, at least one of them transparent for optical examination (for optical examination, col. 15, lines 10-45); at least one wall for holding said containment walls at a distance, and enclosing an interior space, a sample entrance into the first compartment; a means for venting the sample chamber during filling (Fig. 2a). Hillman is silent concerning a separation wall comprising channels. Hillman does teach using filtration techniques within the chamber (col. 9, lines 30-40). Prevost in a device for carrying out filtration teaches a filtering wall for selective filtration (col. 1, lines 35-40). Therefore, it would be obvious to one skilled in the art to have the sample chamber comprise a filtering wall for selective filtration. As for channels, it would have been obvious to one skilled in the art at the time the invention was made that the filtering wall comprises a plurality of channels in order to allow unfiltered constituents and fluid unhampered by the filtering to transit the filtering wall.

b) depositing a liquid sample into the sample entrance of said sample chamber

c) allowing the sample to flow from the sample entrance into the first compartment

d) allowing the sample to advance to the separation wall and the separation channels therein (in view of Prevost above)

e) allowing the sample to advance through the separation wall and the first and second separation channels

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f) allowing the sample to continue to advance until it reaches and stops at the end of the sample chamber

g) obtaining a liquid sample having decreased cellular or particulate concentration (in view of Prevost above)

(col. 19, lines 40-67; col. 20, lines 1-20 of Hillman).

As to **claim 2**, Hillman in view of Prevost discloses everything as above (see **claim 1**).

In addition, Hillman discloses the sample is blood (col. 4, lines 25-30).

As to **claims 6, 7, 19, and 20** Hillman in view of Prevost discloses everything as above (see **claim 1**). They are silent concerning the specific dimensional limitations as claimed by applicant. It would have been an obvious matter of design choice to have the first and second channels and first and second compartments comprise the specific dimensions as claimed by applicant since such a modification would have involved a mere change in the size of a component. A change in size is generally recognized as being within the level of ordinary skill in the art. In re Rose, 105 USPQ 237 (CCPA 1955).

As to **claim 18**, Hillman in view of Prevost discloses everything as above (see **claim 1**). They are silent as to the sizes of compartments in relation to each other. It would have been an obvious matter of design choice to have the second compartment smaller than the first compartment since such a modification would have involved a mere change in the size of a component. A change in size is generally recognized as being within the level of ordinary skill in the art. In re Rose, 105 USPQ 237 (CCPA 1955).

7. **Claims 10, 12, 14, and 16** are rejected under 35 U.S.C. 103(a) as being unpatentable over **Hillman et al. (5,164,598)** in view of **Prevost et al. (5,466,384)** and in evidence of **Wilding et al. (5,635,358)**.

As to **claims 10 and 12**, Hillman in view of Prevost discloses everything as above (see **claim 1**). In addition, Hillman discloses notches, vanes, in the embodiment of Fig. 1b for causing turbulence (Fig. 1b; col. 19 lines 10-20). And Wilding teaches in a fluid handling method of using notches, piercing protrusions, in a cell lyses chamber (col. 8, lines 55-65). Therefore, it would be obvious to one skilled in the art at the time the invention was made to have the interior space or the first compartment of the sample chamber of Hillman's embodiment of Fig. 2a comprise a plurality of notches for producing turbulence.

As to **claims 14 and 16**, Hillman in view of Prevost and in evidence of Wilding discloses everything as above (see **claims 10 and 12**). In addition, Hillman and Wilding discloses the sample flowing past the notches (Fig. 1b, col. 19, lines 10-20 of Hillman; Fig. 1, col. 8, lines 55-65 of Wilding).

8. **Claims 3, 5, 8, 9, 21, 22, and 23** are rejected under 35 U.S.C. 103(a) as being unpatentable over **Hillman et al. (5,164,598)** in view of **Prevost et al. (5,466,384)** and further in view of **Mansky et al. (6,477,479)**.

As to **claim 3**, Hillman in view of Prevost discloses everything as above (see **claim 1**). However, they are silent concerning a moat. Mansky in a method of material characterization teaches providing a moat surrounding a sample support for thermal isolation (col. 16, lines 25-30). Therefore, it would be obvious to one skilled in the art at the time the invention was made to have a moat surrounding the sample chamber to provide thermal isolation.

As to **claim 4**, Hillman in view of Prevost and Mansky discloses everything as above (see **claim 4**). In addition, Hillman discloses the sample is blood (col. 4, lines 25-30).

As to **claims 8, 9, 22, and 23** Hillman in view of Prevost and further in view of Mansky discloses everything as above (see **claim 3**). They are silent concerning the specific dimensional limitations as claimed by applicant. It would have been an obvious matter of design choice to have the first and second channels and first and second compartments comprise the specific dimensions as claimed by applicant since such a modification would have involved a mere change in the size of a component. A change in size is generally recognized as being within the level of ordinary skill in the art. In re Rose, 105 USPQ 237 (CCPA 1955).

As to **claim 21**, Hillman in view of Prevost and further in view of Mansky discloses everything as above (see **claim 3**). They are silent as to the sizes of compartments in relation to each other. It would have been an obvious matter of design choice to have the second compartment smaller than the first compartment since such a modification would have involved a mere change in the size of a component. A change in size is generally recognized as being within the level of ordinary skill in the art. In re Rose, 105 USPQ 237 (CCPA 1955).

9. **Claims 11, 13, 15, and 17** are rejected under 35 U.S.C. 103(a) as being unpatentable over **Hillman et al. (5,164,598)** in view of **Prevost et al. (5,466,384)** and further in view of **Mansky et al. (6,477,479)** and in evidence of **Wilding et al. (5,635,358)**.

As to **claims 11 and 13**, Hillman in view of Prevost and further in view of Mansky discloses everything as above (see **claim 3**). In addition, Hillman discloses notches, vanes, in the embodiment of Fig. 1b for causing turbulence (Fig. 1b; col. 19 lines 10-20). And Wilding teaches in a fluid handling method of using notches, piercing protrusions, in a cell lyses chamber

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(col. 8, lines 55-65). Therefore, it would be obvious to one skilled in the art at the time the invention was made to have the interior space or the first compartment of the sample chamber of Hillman's embodiment of Fig. 2a comprise a plurality of notches for producing turbulence.

As to **claims 15 and 17**, Hillman in view of Prevost and further in view of Mansky and in evidence of Wilding discloses everything as above (see **claims 11 and 13**). In addition, Hillman and Wilding discloses the sample flowing past the notches (Fig. 1b, col. 19, lines 10-20 of Hillman; Fig. 1, col. 8, lines 55-65 of Wilding).

10. **Claim 4** is rejected under 35 U.S.C. 103(a) as being unpatentable over **Hillman et al. (5,164,598)** in view of **Prevost et al. (5,466,384)** and further in view of **Mansky et al. (6,477,479)** and further in view of **Yassinzadeh et al. (5,700,695)**.

As to **claim 4**, Hillman in view of Prevost and further in view of Mansky discloses everything as above (see **claim 3**). However, they are silent concerning the moat comprising a capillary stop. Yassinzadeh in a sample collection and manipulation method teaches using capillary stops to impede capillary flow (col. 1, lines 20-25). Therefore, it would have been obvious to one skilled in the art at the time the invention was made to have the moat comprise a capillary stop in order to impede capillary flow.

Conclusion

11. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

U.S. Patent 4,245,907 to Rosen

U.S. Patent 6,387,325 to Keusch et al.

U.S. Patent 6,448,088 to Levine et al.

Fax/Telephone Numbers

If the applicant wishes to send a fax dealing with either a proposed amendment or a discussion with a phone interview, then the fax should:

- 1) Contain either a statement "DRAFT" or "PROPOSED AMENDMENT" on the fax cover sheet; and
- 2) Should be unsigned by the attorney or agent.

This will ensure that it will not be entered into the case and will be forwarded to the examiner as quickly as possible.

Papers related to the application may be submitted to Group 2800 by Fax transmission. Papers should be faxed to Group 2800 via the PTO Fax machine located in Crystal Plaza 4. The form of such papers must conform to the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989). The CP4 Fax Machine number is: (703) 308-7722

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Gordon J. Stock whose telephone number is (703) 305-4787. The examiner can normally be reached on Monday-Friday, 10:00 a.m. - 6:30 p.m.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0956.

gs

February 8, 2003

Frank Font

Frank Font

Supervisory Primary Examiner

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